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National Voluntary Laboratory Accreditation Program

Chemical Calibration

Providers of Proficiency Testing

C. Douglas Faison
Reenie M. Parris
Stanley D. Rasberry

NIST HANDBOOK 150-19

U.S. Department of Commerce
Technology Administration
National Institute of Standards and Technology

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[1]At Boulder, CO 80303.
[2]Some elements at Boulder, CO.

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PREFACE

NIST Handbook 150-19 presents the technical requirements of the National Voluntary Laboratory Accreditation Program (NVLAP) for accreditation of laboratories that provide chemical calibration to environmental laboratories by means of proficiency testing services. This program is a field of accreditation under the NVLAP Calibration Laboratories program, and may be referred to by the short title *Providers of Proficiency Testing* or by the acronym *PPT*. This handbook is intended for information and use by staff of accredited laboratories, those laboratories seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the accreditation requirements.

This publication supplements NIST Handbook 150, *NVLAP Procedures and General Requirements*, which contains Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR) plus all general NVLAP procedures, criteria, and policies. The criteria in NIST Handbook 150 encompass the requirements of ISO/IEC Guide 25:1990 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987). The provisions of NIST Handbook 150 shall remain in effect for this accreditation program, including the form they may take whenever amended.

The numbering of the sections of NIST Handbook 150-19 is patterned after NIST Handbook 150; for example, Section 285.3 of Handbook 150 presents the description and goal of NVLAP, whereas Section 285.3 of Handbook 150-19 presents the description of the PPT program. Where there is no material specific to this accreditation program, the section number is omitted and does not appear in this handbook.

Any questions or comments on the handbook should be submitted to the National Institute of Standards and Technology/NVLAP, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899-2140; phone: (301) 975-4016; fax: (301) 926-2884; e-mail: nvlap@nist.gov.

ACKNOWLEDGMENTS

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SUMMARY

Any laboratory (including commercial, manufacturer, university, or federal, state, or local government laboratory) that provides proficiency testing to environmental analysis laboratories may apply for NVLAP accreditation. Accreditation will be granted to a laboratory that satisfactorily fulfills the conditions for accreditation defined in NIST Handbook 150, *NVLAP Procedures and General Requirements*, and the requirements defined in this handbook and mirrored in the checklists presented in its appendices. These conditions include satisfactory performance in selected proficiency testing as required, and fulfilling the on-site assessment requirements, including resolution of any identified deficiencies. The names of NVLAP-accredited laboratories are published in the NVLAP annual directory and other media to which information is regularly provided.

(1) A laboratory accredited as a provider of proficiency testing to environmental analysis laboratories, for sake of brevity, will be referred to as a *provider.*

(2) An environmental analysis laboratory which receives proficiency testing from a provider will be referred to as a *laboratory under test.*

Coverage: The analytical and proficiency tests covered include those documented and validated by the provider, the U.S. Environmental Protection Agency (USEPA), and, as appropriate, consensus standards bodies, in the areas of material sampling, material preparation and packaging, analytical determination and chemical analysis, and conduct of tests of proficiency of environmental analysis laboratories. Initially, the scope of accreditation will be limited to proficiency tests for water analysis.

Period of accreditation: One year, renewable annually.

On-site assessment: Visit by one technical assessor or a team of technical assessors to determine compliance with the NVLAP criteria before initial accreditation and every two years thereafter. Additional monitoring visits as required.

Assessors: Technical assessors with appropriate experience.

Proficiency testing: Each provider of proficiency testing is required to participate in proficiency testing as described in Appendix D of this handbook. Periodically, a summary of results is sent to the participants.

Granting accreditation: Accreditation will be granted to a laboratory that satisfactorily fulfills the conditions for accreditation defined in NIST Handbook 150, *NVLAP Procedures and General Requirements*, and the requirements defined in this handbook (including those detailed in the checklists presented in its appendices). These conditions include satisfactory performance in selected proficiency testing as required, and fulfilling on-site assessment requirements, including resolution of any identified deficiencies. A Certificate and Scope of Accreditation are issued to each successful applicant.

Fees: Payments for assessment and accreditation services are required as listed on the NVLAP fee schedule. In addition, fees charged by NIST Analytical Chemistry Division and NIST Ionizing Radiation Division for direct and/or indirect proficiency testing of providers are paid through NVLAP.

Sec. 285.1 Purpose

The purpose of this handbook is to set out procedures and technical requirements for accreditation by NVLAP of laboratories that provide proficiency testing (*providers*) to environmental analysis laboratories (*laboratories under test*). The standards and specifications used by the providers are those published by the U.S. Environmental Protection Agency (USEPA), by consensus standards organizations, and, where appropriate, by the provider, in the areas of material sampling, material preparation and packaging, value-assignment, and conduct of tests of proficiency of environmental analysis laboratories.

The potential range of proficiency tests to be covered by this program is broad and may ultimately include determination of organic and inorganic constituents in air, water, sludge, and solid samples, and biological, microbiological, and radiological tests and analyses. Initially, the program will offer accreditation covering only proficiency tests for water analysis, including microbiological and radiological tests, appropriate for use as described in USEPA National Standards for Water Proficiency Testing Studies: Criteria Document (285.4b).

This handbook complements and supplements the NVLAP programmatic procedures and general requirements found in NIST Handbook 150. The interpretive comments and additional requirements contained in this handbook make the general NVLAP criteria specifically applicable to the Providers of Proficiency Testing program. The quality system requirements are designed to comply with the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002.

Sec. 285.2 Organization of procedures

(a) The handbook is organized to cross-reference with NIST Handbook 150, *NVLAP Procedures and General Requirements*. The format and subject headings used in this handbook, including the checklist found in Appendix B, are consistent with Handbook 150.

(b) The handbook contains five appendices:

(1) Appendix A provides examples of a Certificate of Accreditation and a Scope of Accreditation for the Providers of Proficiency Testing program;

(2) Appendix B provides the General Operations Checklist which NVLAP assessors use during an on-site assessment to evaluate a provider's ability to conduct proficiency testing in general;

(3) Appendix C provides the Specific Operations Checklist which NVLAP assessors use during an on-site assessment of a laboratory that is a provider of proficiency testing;

(4) Appendix D lists the procedures that NIST will use for testing the proficiency of providers; and

(5) Appendix E lists the proficiency test programs available for inclusion in a scope of accreditation.

Sec. 285.3 Description of the Providers of Proficiency Testing program

This program provides accreditation only to those laboratories that can demonstrate their capabilities and competence to provide proficiency testing (PT) services to environmental analysis laboratories.

Environmental analysis laboratories may participate in accreditation programs separate from this one. Typically, those programs accredit the laboratory's analytical capabilities for use by customers providing data to the U. S. Environmental Protection Agency, and individual states. Analytical fields include drinking water and waste water compliance monitoring and ground and surface water quality monitoring.

To achieve and maintain accreditation, environmental analysis laboratories must demonstrate their competence by periodically participating in a proficiency testing program. It is the providers of the PT services that are addressed by the accreditation program described in this handbook. In general, PT service providers will distribute samples from lots of well-characterized, but with characterization not revealed, materials to environmental analysis laboratories. By evaluating the results produced by the laboratories under test, the PT service provider can furnish accrediting bodies with indications of the performance of tested laboratories.

In order to be accredited under the program described in this handbook, providers of proficiency testing must undergo periodic on-site technical assessment of

competence. Also, periodically they must demonstrate their proficiency in accurately characterizing the samples they distribute and the methods they employ in conducting proficiency tests. The procedures for conducting these assessments and demonstrations are found in this handbook.

Sec. 285.4 References

References and sources for the Providers of Proficiency Testing program follow:

(a) NIST Handbook 150, *NVLAP Procedures and General Requirements*, March 1994 (this handbook incorporates ISO/IEC Guide 25 in its entirety); available from:

NIST/NVLAP
100 Bureau Drive, Stop 2140
Gaithersburg, MD 20899-2140

Phone: (301) 975-4016
Fax: (301) 926-2884
E-mail: nvlap@nist.gov
Website: ts.nist.gov/nvlap;

(b) U.S. Environmental Protection Agency *National Standards for Water Proficiency Testing Studies: Criteria Document*, December 1998 (and/or updated version(s) as applicable); available from:

U.S. Environmental Protection Agency
NERL, EERD, NWQAPB
26 West M. L. King Drive, Room 525
Cincinnati OH 45268;

(c) National Environmental Laboratory Accreditation Conference (NELAC) Standards, July 2, 1998 version (and/or updated version(s) as applicable); available from:

National Environmental Laboratory
Accreditation Program (NELAP)
U.S. Environmental Protection Agency
401 M Street, SW (8724R)
Washington, DC 20460

Website: www.epa.gov/ttn/nelac;

(d) NIST Technical Note 1297, 1994 ed., *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, September 1994; available from NVLAP (see (a) above);

(e) *Quantifying Uncertainty in Analytical Measurements*, English ed., Eurachem, 1995; available from:

BSI Customer Services
389 Chiswick High Road
London W4 4AL, United Kingdom;

(f) ISO Standard 9002 (ANSI/ASQC Q9002), *Quality Systems—Model for Quality Assurance in Production, Installation, and Servicing*, 1994;

(g) ISO/IEC Guide 25, *General requirements for the competence of calibration and testing laboratories*, 1990 [Note: The requirements of ISO/IEC Guide 25 are contained in NIST Handbook 150 as Section 285.33.];

(h) ISO Guide 30, *Terms and definitions used in connection with reference materials*, 1992;

(i) ISO Guide 34, *Quality system guidelines for the production of reference materials*, 1996;

(j) ISO Guide 35, *Certification of reference materials - general and statistical principles*, 1989;

(k) ISO/IEC Guide 43, *Proficiency testing by interlaboratory comparisons, Part 1 and Part 2*, 1997;

(l) ISO/IEC/BIPM *International Vocabulary of Basic and General Terms in Metrology*, 2nd ed., 1993;

(m) ISO/IEC/BIPM *Guide to the Expression of Uncertainty in Measurement*, 1993;

(n) For Providers of Radiochemistry Proficiency Testing: ANSI N42.22-1995, *American National Standard - Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control*, 1995;

(o) For Providers of Radiochemistry Proficiency Testing: ANSI N42.23-1996, *American National Standard - Measurement and Associated Instrument Quality Assurance for Radioassay Laboratories*, 1996;

The documents listed as items **(f) - (o)** are available from:

American National Standards Institute (ANSI)
11 West 42 Street, 13th Floor
New York, NY 10036

Order phone: (212) 642-4900
Order fax: (212) 302-1286;

(p) *The International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories*, Journal of AOAC International, 76 (4), 926-940, 1993; available from:

AOAC International
First Union National Bank Lock Box
P. O. Box 75198
Baltimore, MD 21275-5198

Phone: (800) 379-2622
Fax: (301) 924-7087

(q) ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*; available from:

National Conference of Standards Laboratories (NCSL)
1800 30th Street, Suite 305B
Boulder, CO 80301-1032

Phone: (303) 440-3339
Fax: (303) 440-3384
E-mail: ncsl-staff@ncsl-hq.org

Sec. 285.5 Definitions (additional to those found in Handbook 150)

Accuracy of measurement: Closeness of the agreement between the result of a measurement and a true value of the measurand [*International Vocabulary of Basic and General Terms in Metrology* (VIM), 3.5].

Assigned value: Value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose. [See VIM, 1.20.] Assigned value is formally named *conventional true value (of a quantity)* in the VIM.

Consensus standards organization: The American National Standards Institute (ANSI), International Organization for Standardization (ISO), and any other organization recognized by the U. S. Environmental Protection Agency as a provider of appropriate standards.

Laboratory under test: An environmental analysis laboratory that receives proficiency testing from a provider of proficiency testing.

Proficiency test (PT): In this program, a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown materials provided by an external provider of proficiency testing.

Proficiency Test Material (PTM): A material that is well characterized for its stability, homogeneity, and property values, but has the property values unrevealed so it can be circulated to laboratories under test to evaluate their proficiency in analyzing or testing the material.

Providers of Proficiency Testing (PPT): For brevity, *Providers*; laboratories that design PTs, prepare, value-assign, and distribute PTMs, and collect, evaluate and report results returned by laboratories under test.

Standard Reference Material (SRM): A reference material certified and distributed by the National Institute of Standards and Technology (NIST).

Standards and specifications: The provisions of a document published by a consensus standards organization, or a government agency.

Sec. 285.6 NVLAP documentation

(a) Program Selection List

(1) Depending on the breadth of its capabilities, a provider may seek accreditation for some or all of the proficiency tests offered in the PPT program. The Program Selection List, provided to the laboratory seeking accreditation as part of the NVLAP application package, lists the available proficiency test programs. Appendix E lists the programs currently available for accreditation. Initially, the NVLAP program and a provider's scope of accreditation will be limited to proficiency tests for water analysis.

(2) Requests to have proficiency test programs added to Appendix E will be handled in accordance with NVLAP procedures (see Handbook 150, Sec. 285.18).

(b) Checklists

Checklists contain definitive statements or questions about all aspects of the NVLAP criteria for accreditation. NVLAP programs incorporate two types of checklists:

(1) The NVLAP General Operations Checklist addresses factors applicable to evaluating a provider's ability to conduct testing in accordance with the procedures and general requirements for accreditation. The factors include, but are not limited to, the provider's organization, management, and quality system in addition to its testing competency.

The General Operations Checklist, presented in Appendix B, is numbered to correspond to the requirements in NIST Handbook 150. The comment sheets are used by the assessor to explain findings and deficiencies noted on the checklist, as well as to make comments on aspects of the provider's performance other than deficiencies.

(2) The Specific Operations Checklist contains statements or questions that are specific to the Providers of Proficiency Testing program. This checklist is presented in Appendix C, along with comment sheets similar to those used with the General Operations Checklist.

Sec. 285.22 Assessing and evaluating a provider

(a) On-Site Assessment

(1) The NVLAP Lead Assessor will be supplied manuals and/or documented procedures by the provider to be assessed, in advance of the on-site assessment to reduce the time spent on-site. Documents supplied in advance will be returned. The provider should be prepared for conducting analytical demonstrations, have equipment in good working order, and be ready for examination according to the requirements identified in this handbook, NIST Handbook 150, and the provider's quality manual. The assessor will need time and work space to complete assessment documentation during the visit.

(2) The checklists found in Appendices B and C will be used by the assessor, or assessment team, to help assure the completeness, objectivity, and uniformity of the on-site assessment. The assessment will include a review of the provider's ability to perform appropriate preparation and characterizations of PT materials and to perform appropriate proficiency testing procedures. The review ranges from observing tests to having laboratory staff describe or demonstrate the procedures. The assessor notes the depth into which each part of a specific operational procedure was reviewed and records the results of the review on the specific operations checklist comment sheet.

(3) An assessor or assessment team performs the following activities during a typical on-site assessment:

(i) Conducts an entry briefing with the manager to explain the purpose of the on-site visit and to discuss the schedule for the day(s). The assessment team attends and, at the discretion of the manager, other staff may attend the briefing.

(ii) Reviews provider records and documents. At least one provider staff member must be available to answer questions; however, an assessor may wish to review documents alone.

(iii) Physically examines equipment and facilities and observes the demonstration of selected procedures by appropriate personnel, and interviews the personnel. The demonstrations requested may be selective or all-inclusive, and must include sampling of material(s), preparation and packaging of materials, setup/use of major equipment, establishment of test conditions, and the operational aspects of conducting the proficiency testing of environmental analysis laboratories. Such operational aspects shall include, but not be limited to, the design of one complete PT study, material distribution plan, instruction sets, security measures, data collection system, data evaluation methodology, and results reporting.

(iv) Completes an On-Site Assessment Report that contains the minimum requirements prescribed in NIST Handbook 150 and copies of the completed checklists. At the exit briefing, the report is signed by the Lead Assessor and the provider's Authorized Representative to acknowledge the discussion, but does not necessarily indicate agreement; challenge(s) may be made through NVLAP. All observations made by NVLAP assessors are held in the strictest confidence.

(b) Proficiency Testing of Providers

(1) The proficiency testing program for evaluation of providers of proficiency testing services will be conducted by technical divisions of the National Institute of Standards and Technology. The tests will be conducted according to the provisions of Appendix D of this handbook.

(2) Proficiency testing will follow one of two models, as required by the NIST technical division and as described in Appendix D of this handbook. The two models are briefly described as follows:

(i) *Direct Proficiency Testing*. In this conventional model, materials will be sent by NIST to providers of proficiency testing as unknowns for analysis. After completion of the analyses, each provider will return its results to NIST for statistical evaluation.

(ii) *Indirect Proficiency Testing*. In this model, each provider of proficiency testing will submit to NIST a portion of each lot of material distributed in the PT studies that it operates. NIST can then evaluate the proficiency of the provider by comparing NIST results with the provider's assigned values. Where this approach can be used, it offers the possibility of 100% surveillance of distributed materials, in addition to allowing NIST to evaluate the provider's proficiency.

Sec. 285.23 Granting and renewing accreditation

Providers granted NVLAP accreditation receive two documents: a Certificate of Accreditation and a Scope of Accreditation. Samples of these accreditation documents for the Providers of Proficiency Testing program are shown in Appendix A. Note that the Certificate states that the criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987).

Sec. 285.24 Denying, suspending, and revoking accreditation

Failure to comply with all NVLAP requirements, as specified in this handbook and in NIST Handbook 150, may result in the denial, suspension, or revocation of a laboratory's accreditation. This includes failure to resolve noted deficiencies and failure to successfully participate in proficiency testing activities.

Sec. 285.33 Criteria for accreditation

(c) Quality system, audit and review

(1) The provider shall define and document its quality procedures for obtaining accurate and precise analytical data, and for the conduct of proficiency test studies. These procedures shall be the benchmarks by which the management assesses overall and individual performance.

(2) Under its quality system, the provider shall develop and implement procedures covering all the technical requirements of this handbook. Professional staff shall be able to obtain enough information from the provider's quality documentation to perform their work in the absence of the manager. Periodic management reviews of the quality system shall reflect adherence to NVLAP requirements and the provider's quality procedures. These reviews should reflect positive aspects of the quality system as well as deficiencies.

(3) The quality manual shall describe the provider's staff, facilities and equipment, test procedures, calibration procedures, material custody and handling procedures, and test report format and procedures. The quality system documentation shall contain:

(i) specific records (or reference to records) of material preparation, packaging and storage locations;

(ii) provisions for routine quality assurance checks to verify overall methodology;

(iii) examples of designs for conducting proficiency tests;

(iv) filled-in examples of all standardized forms used by the provider; and

(v) procedures for storage and retrieval of records.

(4) The provider's quality assurance checks shall be performed routinely, covering all time periods, material types, instruments, tasks, and personnel. The selection of samples for quality assurance checks shall be semirandom and, when possible, the specific checks on personnel performance shall be executed without their prior knowledge. A disproportionate number of practice (i.e., "training" or "tune-up") analyses shall not be performed prior to internal or external audits. Quality assurance activities shall not be postponed during periods of heavy work loads.

(5) The provider shall conduct quality assurance activities on a frequent enough basis to detect problems.

(6) Laboratories seeking accreditation under the Providers of Proficiency Testing program shall have available a copy of all references listed under checklist item 2.1 of Appendix C of this handbook.

(d) Personnel

(1) Employees shall be aware of the extent of their area of responsibility. This information shall be available in the required job descriptions found in the quality documentation and individual files.

(2) The provider shall have a written description of its training program including its criteria for successful completion. The provider shall establish and document performance criteria to determine when a new analyst is qualified to perform work assigned in this program.

(3) Analysts, technicians, and technical supervisors shall participate in an appropriate form of continuing education, such as formal course work, in-house education, and scientific or technical meetings, and have access to journals that describe advances in the fields of analysis and testing.

(4) Analyst competence is important to providing reliable data. All analysts shall be tested routinely to evaluate their performance. Test results shall be recorded in the personnel folder or equivalent of each staff member, and be available for review during NVLAP on-site assessments. Testing shall be frequent enough to ensure quality analyses. Problems shall be discussed with the analyst, and corrected according to documented procedures. Subsequent quality assurance tests shall determine whether the problem has been corrected. The provider shall ensure the quality of analyses while the problem is being corrected. All corrective actions shall be documented in quality assurance summaries, periodic laboratory audits, and individual analyst's files.

(5) Technical staff competence is important to conducting valid proficiency tests. All technical staff members who design and conduct proficiency tests, including those who distribute materials, collect data, process data, and prepare reports, shall be tested routinely to evaluate their performance. Testing may take various forms, including oral review of procedures with a supervisor to demonstrate understanding of all appropriate procedures, and review of results of recent performance. Testing shall be frequent enough to ensure quality of staff performance. Problems shall be discussed with the staff member(s), and corrected according to documented procedures. Subsequent reviews shall determine whether the problem has been corrected. The provider shall ensure the quality of the proficiency test studies conducted while the problem is being corrected. All corrective actions shall be documented in quality assurance summaries, periodic audits, and individual personnel files.

(6) The provider shall be organized so that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work. The provider shall be able to demonstrate that work loads are consistent with provision of high-quality proficiency testing services.

(7) The provider will be responsible for demonstrating its competence to value-assign PT materials following the practice outlined in its quality documentation. Any staff members involved in the value-assignment of PT materials will be responsible for demonstrating their competence as required during an on-site assessment.

(e) Accommodation and environment

(See NIST Handbook 150.)

(f) Equipment and reference materials

(1) All equipment shall be properly maintained to ensure protection from contamination, corrosion, and other forms of deterioration. Instructions for proper maintenance of equipment that requires periodic maintenance must be available. Any equipment or component thereof that has been subjected to contamination or critical mishandling, gives suspect results, or has been shown to be defective, must be taken out of service and clearly labeled until it has been repaired. When placed back in service, this equipment must be demonstrated as performing its functions satisfactorily.

(2) Where available, the provider shall have appropriate reference materials and their associated certificates to be used in evaluation of personnel, calibration of equipment and/or measurement processes, and validation of measurement processes.

(3) The provider shall maintain procedures for ensuring and documenting that automated test systems function properly and are used properly.

(g) Measurement traceability and calibration

(1) Instrument and measurement process calibrations will be performed by properly trained staff using calibrated standards, including Standard Reference Materials, which are traceable to NIST or by using a laboratory accredited by NVLAP or by an accrediting body recognized by NVLAP through a Mutual Recognition Arrangement (hereinafter referred to as *appropriately accredited*). If available, all calibrations and characterizations must be done using reference standards that are traceable to national standards maintained by NIST or by a foreign national standards authority, recognized by NIST, that issues reference or calibration materials. If appropriate national standards are not available, calibration materials such as a calibrant independently prepared using a well-characterized, different raw material source, or one prepared and documented by a source external to the provider may be used. It is the responsibility of the provider seeking accreditation to determine that, where appropriate, calibration services use reference standards traceable to NIST or to a recognized foreign national standards authority.

(2) Certificates, records, and evidence of the traceability of the reference standards used must be retained and made available for review during the on-site visit. The certificates should indicate certified values and uncertainties and traceability of reference standards. If calibration is performed by the provider, the standard metrological procedures used, the environmental conditions, and the measurement uncertainty must be documented. Certificates are required for calibration performed by outside services; they are not required for testing equipment used in measurements unrelated to value assignment.

The records for each calibration and value-assignment shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration, analyzing, or testing.

(3) In addition to the information specified in NIST Handbook 150, Sec. 285.33(f)(4), testing equipment records shall include the following:

(i) notation of all equipment variables requiring calibration;

(ii) the range of calibration;

(iii) as appropriate, the resolution, detection limit, and sensitivity of the instrument and its allowable error;

(iv) identity of the person or company responsible for service and calibration of the instrument; and

(v) source of reference standards and traceability.

(h) Calibration and test methods

(1) For each PT study, a plan or design shall be available, in advance, that provides for USEPA and state requirements, and at a minimum, the following information:

(i) unique identification for the specific PT study;

(ii) chronology for the PT study;

(iii) specific instructions to the laboratories under test;

(iv) specific procedures by which the returned data will be analyzed;

(v) procedures for reporting the results of the PT studies;

(vi) reference to security procedures and any additional security measures specific to the given PT study;

(vii) procedures for assuring adequate challenge to the laboratory under test and other relevant requirements; and

(viii) procedures for assuring that PT material/study design is appropriate for its use with program-designated performance evaluation criteria to be used by the provider to evaluate laboratories under test.

(2) Providers shall use validated methods that are appropriate to the material being value-assigned and that are consistent with the uncertainty criteria that are in place for the given method at the time of the value-assignment. The provider must have a copy of all uncertainty criteria, standards, and validated test methods that it uses in the proficiency testing programs for which it seeks accreditation.

(3) Proficiency testing covered in the Providers of Proficiency Testing program is divided into four major areas:

(i) inorganic chemical analysis;

(ii) organic chemical analysis;

(iii) biological and microbiological testing; and

(iv) radiological testing and analysis.

(4) The provider's laboratory shall conform in all respects with the validated method employed to assign a value to a proficiency test material. A provider will validate each method used by comparison with Standard Reference Materials certified and issued by the National Institute of Standards and Technology, unless appropriate SRMs are not available, or the provider can show an alternative, and convincing, demonstration of traceability to national standards.

(5) Providers will be granted accreditation only for the proficiency test programs for which they apply and are found competent to perform under NVLAP criteria.

(6) Prior to distribution of a material for use in a PT study, the provider shall assess the homogeneity and stability of the material and the accuracy and total uncertainty of each assigned value derived from provider material preparation and/or analyses data to ensure that the material is suitable for use. Specific performance criteria listed in this section are minimum standards and, as such, may not be sufficient to ensure the suitability of a given PT material; the provider is responsible for producing PT materials that are fit for purpose. The USEPA criteria document specifies that the provider use the value determined by the way the material is formulated, such as with known amounts of weighed substances of assessed purity, as the basis for assigned value and acceptability criteria for PT parameters with the exception of a few parameters in which the provider is to use the study data to establish acceptability criteria. The USEPA document defines an acceptable range for the reported PT value of a laboratory under test for most analytes of concern as the assigned value $\pm$ acceptance limits calculated from the assigned value.

The repeatability of the validated measurement method(s) used for these material and value-assignment assessments should be sufficient to detect any significant heterogeneity or instability in the PT materials or errors in the prepared values. At a minimum, the method repeatability, expressed as a standard deviation, shall be less that one-sixth of the acceptance limits of the laboratory under test as calculated for the analyte of interest to a maximum of 5% of the prepared value (or "estimated mean recovery" if appropriate).

The provider shall include:

(i) for each material in which the prepared value is used as the basis for determining acceptability of the laboratories under test, a quality check in which appropriate, validated methods are used to analyze the PT material for each analyte of interest for comparison with appropriate reference materials (see 285.33 (g) and 285.33 (h)(1)) to check for any major production errors in material preparation. At a minimum, for each analyte the provider's quality check analytical mean should be within a range defined by the prepared value (or in applicable cases, the USEPA "estimated mean recovery" [as defined in the USEPA criteria document]) ± one-third of the acceptance limits as calculated for the laboratories under test to a maximum of ± 10% of the prepared value (or "estimated mean recovery" if appropriate).

(ii) a homogeneity check conducted prior to use of the material in a PT study to establish at the 95% confidence level through appropriate analyses of a statistically valid subset of the packaged PT materials that the measured value of each parameter is consistent across the units of PT material produced for a given study; i.e., that for each component analyte that there is no significant heterogeneity within the sample pool.

(iii) a stability assessment to establish at the 95% confidence level through appropriate analyses of a statistically valid subset of the packaged PT materials that the measured value of each parameter is consistent across the time period of the given study (commencing immediately after formulation for those PT materials in which any prepared value(s) is used as the basis for an assigned-value).

(7) The provider shall have written procedures to address all aspects of producing materials for use in proficiency testing (e.g., sampling, sample preparation, homogeneity assessment, value-assignment, packaging, storage, and stability verification, etc.), for the conduct of the study, and for reporting of the study results.

(i) Handling of calibration and test items (the proficiency test materials)

(1) The provider shall have written procedures covering all aspects of procuring, preparing, handling, and storage of component source materials and PT materials. The log-in system shall include documentation of the date(s) of receipt or production, unique identification for the material, condition of the material, and the acceptance or rejection of the material. The provider shall have written criteria for acceptance or rejection of these materials.

(2) The provider shall have a chain-of-custody system that documents the following information:

(i) location of the material;

(ii) personnel who have handled or worked with the material; and

(iii) what has been done to the material.

The system for identifying PT materials, and component source materials, must remain in force from the date of procurement of the material to the date of its disposal, either through documents or through marking, to ensure that there is no confusion regarding the identity of the materials and the results of the measurements.

(j) Records (also see Specific Operations Checklist)

(1) Records may be kept in hard copy form, and must be available in a specified computer format (with an adequate back-up system.) They shall be readily accessible to authorized use and secure from unauthorized use. The period of retention shall be 5 years (the minimum period suggested by states, USEPA, and NELAC), unless a longer period is required by the client, regulation, or the provider's own procedures. Procedures for storage and retrieval of records must be documented and maintained in the provider's quality system documentation. Records shall be stored in a logical fashion allowing retrieval within one working day.

(2) A security system must be in place and practiced that will reliably prevent dissemination of material assigned values prior to the

conclusion of a proficiency test study. The system must also secure records against inappropriate release of information regarding the performance of any tested environmental laboratory.

(k) Certificates and reports

(See NIST Handbook 150.)

(l) Subcontracting

(1) Except as provided in (2), for each PT study, the work is performed, results are obtained, and the reports are prepared by the personnel, using equipment and procedures of the provider of that study. However, in some cases a provider may require the use of another facility due to equipment failure, need for specialized equipment, or to perform tests outside the provider's own scope of accreditation.

(2) Whenever a provider subcontracts to a laboratory the performance of any work, test, or portion of a test associated with a proficiency test it must:

(i) place the work with a laboratory that is appropriately accredited;

(ii) document, as part of the information and instructions provided to clients, the extent of that subcontracting; and

(iii) clearly identify in its records, and in all reports to the clients, specifically which test method(s) or portions of a test method(s) were performed in-house and which were performed by the subcontractor.

(m) Outside support services and supplies

(See NIST Handbook 150.)

(n) Complaints

(See NIST Handbook 150.)

(o) Operation of proficiency test studies

(1) Distribution of PT materials and instructions

(i) Demonstration must be available that all applicable shipping and safety regulations are met.

(ii) Material Safety Data Sheets (MSDS) must be available for all materials that require them and they must be distributed appropriately with any shipment where they are required.

(iii) Instructions to the laboratory under test must be provided in such manner that it is clear that the instructions are to remain with the material through all stages of shipment and handling, until they have reached the personnel who are responsible for analysis or testing.

(iv) The mode of shipment and the procedures for shipment must assure the integrity of the material and prevent any compromise to its integrity.

(v) Shipping records must provide adequate information to track custody of the material and to permit recall, if necessary.

(2) Collection and evaluation of PT data

(i) Providers of proficiency testing will give detailed instructions to laboratories under test regarding how they are to format and transmit the results of their test.

(ii) Providers will evaluate results and record performance levels according to currently applicable criteria published by the USEPA to assure equal treatment of tested laboratory results. Any specific study parameter causing anomalous study results for reasons such as previously unrecognized significant instability, inhomogeneity, or inaccurately assigned values will not be used in evaluating laboratories under test and should be identified in all reports to laboratories under test and accrediting authorities.

(3) **Reporting the results of proficiency test studies of laboratories under test**

(i) Reference to the published evaluation criteria used, e.g., USEPA "National Standards for Water Proficiency Testing Studies: Criteria Document," will be cited in all reports.

(ii) Results of proficiency test studies will be developed in several forms:

- a data report form will be received by the PT provider from each participating laboratory under test;
- uncoded individual laboratory results that must be secure from unauthorized distribution;
- complete sets of individual results for all participating laboratories with laboratory designations so coded or obscured that no other security is required;
- summary results that do not reveal individual laboratory results, and that do not require security measures; and
- a study discussion report that provides closure for a given study and addresses any details of the study that were unusual.

(iii) Results of proficiency test studies will be distributed as follows:

- for each study, summary results and a discussion report will be provided to the participating laboratories, USEPA, NIST, and appropriate accrediting bodies in an electronic format as specified by USEPA, and may be widely published;
- complete sets of individual results (with laboratory designations coded) will be made available to USEPA, NIST, accrediting bodies, and participating laboratories in a specified electronic format, and may be widely published;
- uncoded individual laboratory results will be provided to the specific laboratory referenced in the results and, by request and release by that specific laboratory, to its accrediting body or bodies; and
- uncoded individual laboratory results will be made available to USEPA and NIST by implied consent through participation of the tested laboratory, but they will not be published by NIST.

APPENDIX A

SAMPLE ACCREDITATION DOCUMENTS

United States Department of Commerce
National Institute of Standards and Technology

NVLAP®

ISO/IEC GUIDE 25:1990
ANSI/NCSL Z540-1-1994
ISO 9002:1987

Certificate of Accreditation

DEPARTMENT OF COMMERCE ★ UNITED STATES OF AMERICA ★

LABORATORY NAME
ANYTOWN, USA

is recognized under the National Voluntary Laboratory Accreditation Program for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. Accreditation is awarded for specific services, listed on the Scope of Accreditation for:

CHEMICAL CALIBRATION: PROVIDERS OF PROFICIENCY TESTING

March 31, xxxx
Effective through

For the National Institute of Standards and Technology

NVLAP-02C (11-95)

NVLAP LAB CODE: 000000-0

National Institute of Standards and Technology

NVLAP®

National Voluntary Laboratory Accreditation Program

ISO/IEC GUIDE 25:1990
ANSI/NCSL Z540-1-1994
ISO 9002:1987

Scope of Accreditation

CHEMICAL CALIBRATION:
PROVIDERS OF PROFICIENCY TESTING

NVLAP LAB CODE 000000-0

LABORATORY NAME
Street Address
Anytown, USA 00000-0000
Mr. John Doe
Phone: 000-000-0000 Fax: ###-###-####

NVLAP Code	*Designation & Title*
USEPA WSCHEM	
20/U01	Trace Metals
20/U02	Sodium
20/U03	Nitrate, Nitrite, Fluoride, and Orthophosphate
20/U04	Bromate, Bromide, Chlorate, and Chlorite
USEPA WSMICRO	
20/U27	Coliform (Presence/Absence)
USEPA WPCHEM/DMRQACHEM	
20/U28	Trace Metals
20/U29	Minerals: Calcium, Magnesium, Potassium, and Sodium

March 31, xxxx
Effective through

For the National Institute of Standards and Technology

NVLAP-02S (11-95)

APPENDIX B

GENERAL OPERATIONS CHECKLIST

Note: Appendix B is a standardized and controlled NVLAP document. It is specifically correlated to NIST Handbook 150, and is used in identical form in every NVLAP program. In order to preserve an exact match among all NVLAP programs, alterations to Appendix B are permitted only when all NVLAP handbooks are revised.

As a practical matter, assessors (with a background in chemical measurements) using the Appendix B checklist for assessments under this program shall take into account adjustments in terminology that are needed to adapt usage to this program. For example, the term *measurement* will be understood to include the concepts *chemical analysis* and *analysis*. *Calibration* is understood, in the general sense, to include *analytical validation*. *Test items* include *samples of material* and *proficiency test materials*. *Measuring and test equipment* includes *analytical instruments*.

Assessments are to be made based on appropriate substitution of these analogous terms and concepts. For example, the assessor (who will be an expert in chemical analysis) will use the General Operations Checklist to guide general assessment of the provider's preparation and handling of materials, traceability of reference materials, treatment of personnel, suitability of facilities, care and validation of analytical instruments, recordkeeping and reporting, and general operation of proficiency test studies including treatment of customers and other stakeholders. Additional guidance to the assessor that is specific to this accreditation program is found in Appendix C.

GENERAL OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses general accreditation criteria prescribed in applicable sections of NIST Handbook 150, *NVLAP Procedures and General Requirements*.

This checklist follows and is numbered to correspond to the *NVLAP Procedures and General Requirements*, Subsection 285.33. The numbers in square brackets identify related checklist items. A small black triangle appears in the left-hand margin of selected lines of text throughout this checklist; the marked text applies only to the Calibration Laboratory Accreditation Program (LAP).

Place an "X" beside each checklist item which represents a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments in this list or on the attached comment sheets. Place a check beside all other items you observed or verified at the laboratory.

SEC. 285.33 CRITERIA FOR ACCREDITATION

(b) ***Organization and management***

(1) The laboratory shall be:

_____ (i) legally identifiable;

Legal name of laboratory ownership: _____

(ii) organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the NVLAP requirements [see also (b)(2)(i), (c)(2)(ii)];

_____ (iii) properly identified on the NVLAP Application.

(2) The laboratory shall:

_____ (i) have managerial staff with the authority and resources needed to discharge their duties [see also (b)(1)(ii), (c)(2)(ii)];

_____ (ii) have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

_____ (iii) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

_____ (iv) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

_____ (v) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

_____ (vi) have a technical manager (however named) who has overall responsibility for the technical operations;

Name of person: _____

_____ (vii) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

Name of person: _____

_____ (viii) nominate deputy(ies) in case of absence of the technical or quality manager;

Name(s): _____

_____ (ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights [see also (c)(2)(xviii)];

_____ (x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs [see also (c)(2)(xiv), (c)(6)(ii), (g)(3)];

_____ (xi) have documented policy and procedures to ensure that its clients are served with impartiality and integrity.

(c) ***Quality system, audit and review***

(1) The laboratory shall:

_____ (i) have an established and maintained quality system appropriate to the type, range and volume of calibration and testing activities it undertakes;

_____ (ii) have the elements of the quality system documented;

_____ (iii) ensure that the quality documentation is available for use by the laboratory personnel;

_____ (iv) define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services;

_____ (v) have the laboratory management which ensures that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned;

_____ (vi) ensure that the quality manual is maintained current under the responsibility of the quality manager [see also (c)(2)(iv)].

Date of quality manual: _____

Date of latest update: _____

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the NVLAP requirements. The quality manual and related quality documentation shall contain:

_____ (i) a quality policy statement, including objectives and commitments, by top management;

_____ (ii) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

_____ (iii) the relations between management, technical operations, support services and the quality system;

_____ (iv) procedures for control and maintenance of documentation [see also (c)(1)(vi), (j)(1)];

_____ (v) job descriptions of key staff and reference to the job descriptions of other staff;

_____ (vi) identification of the laboratory's approved signatories (list here or in the comments section): _____

_____

_____ (vii) the laboratory's procedures for achieving traceability of measurements;

_____ (viii) the laboratory's scope of calibrations and/or tests;

_____ (ix) written procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

_____ (x) reference to the calibration, verification and/or test procedures used;

_____ (xi) procedures for handling calibration and test items;

_____ (xii) reference to the major equipment and reference measurement standards used;

_____ (xiii) reference to procedures for calibration, verification and maintenance of equipment;

_____ (xiv) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes [see also (b)(2)(x), (c)(6)(ii), (g)(3)];

(xv) procedures to be followed for feedback and corrective action whenever:

_____ a) testing discrepancies are detected, or

_____ b) departures from documented policies and procedures occur;

_____ (xvi) the laboratory management policies for departures from documented policies and procedures or from standard specifications;

_____ (xvii) procedures for dealing with complaints [see also (n)];

_____ (xviii) procedures for protecting confidentiality and proprietary rights [see also (b)(2)(ix)];

_____ (xix) procedures for audit and review;

_____ (xx) a description of the laboratory's policy regarding the use of the NVLAP logo;

▸ _____ (xxi) a statement of the laboratory's policy for establishing and changing
▸ calibration intervals for equipment it controls; and

_____ (xxii) a statement of the laboratory's policy concerning the technique(s) to be used for determining measurement uncertainty and calibration/verification adequacy.

_____ (3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

The audits shall be objective and be conducted internally or on contract. The audits shall include both general criteria (documents, records and policies) and technical compliance (test methods and practices and calibration procedures).

_____ (4) The quality system adopted to satisfy the NVLAP requirements shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

_____ (5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

_____ (i) internal quality control plans, such as control charts and other available statistical techniques;

NOTE: Measurement assurance techniques are acceptable means to control the measurement process and consistently produce the highest quality measurements.

_____ (ii) participation in proficiency testing or other interlaboratory comparisons [see also (b)(2)(x), (c)(2)(xiv), (g)(3)];

_____ (iii) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

_____ (iv) replicate testings using the same or different methods;

_____ (v) retesting of retained items;

_____ (vi) correlation of results for different characteristics of an item.

(d) ***Personnel*** [see also (c)(2)(v)]

_____ (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

_____ (2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

_____ (3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) ***Accommodation (facilities) and environment*** [see also (i)(3)]

_____ (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

NOTE: Laboratory design will be, to the maximum extent practical, in accordance with the guidelines found in the NCSL Recommended Practice #7, *Laboratory Design*, July 25, 1993.

_____ (2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

NOTE: It is expected that environments which do not meet generally accepted norms, such as those found in NCSL Recommended Practice #7, yet which exhibit the stability required to apply necessary correction factors, will be specified by the laboratory for the purpose of assessment of compliance with its own procedures to achieve its stated uncertainties.

_____ (3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

_____ (4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

_____ (5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

_____ (6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE: While it is the laboratory's responsibility to comply with relevant health and safety requirements, this is outside the scope of this assessment.

(f) ***Equipment and reference materials***

(1) The laboratory shall:

_____ (i) be furnished with all items of equipment (including hardware, software, and reference materials) required for the correct performance of calibrations and tests;

_____ (ii) in those cases where the laboratory needs to use equipment outside its permanent control, including rented, leased and client-owned equipment, ensure that the relevant NVLAP requirements are met.

_____ (2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

_____ (3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

_____ (4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

_____ (i) the name of the item of equipment, software or reference material;

_____ (ii) the manufacturer's name, type identification, and serial number or other unique identification;

_____ (iii) date received and date placed in service;

NOTE: For initial accreditation, the date received and the date placed in service are not considered mandatory requirements for inclusion in laboratory records, although this is encouraged as good laboratory practice.

_____ (iv) current location, where appropriate;

_____ (v) condition when received (e.g., new, used, reconditioned);

_____ (vi) copy of the manufacturer's instructions, where available;

_____ (vii) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

_____ (viii) details of maintenance carried out to date and planned for the future;

_____ (ix) history of any damage, malfunction, modification or repair;

► _____ (x) measured value observed for each parameter found to be out of tolerance
► during calibration/verification.

(g) ***Measurement traceability and calibration***

_____ (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

_____ (2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall, wherever applicable, indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

NOTE: Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries where applicable. In these cases, traceability is achieved via international standards. This includes intrinsic standards of measurement where available.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*: 1993, shall be used as the basis for expression of uncertainty of the measurement. NIST Technical Note 1297; January 1993, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement*. Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of test accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

NOTE: A significant number of intrinsic standards, such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard, have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials, and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means, that its intrinsic standard measurement results are correlated with those of national or international standards.

_____ (3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing [see also (b)(2)(x), (c)(2)(xiv), (c)(6)(ii)].

NOTE: Traceability requirements may also be satisfied by:

(i) internationally accepted standards in the field concerned;

(ii) suitable reference materials;

(iii) ratio or reciprocity measurements; or

(iv) mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.

_____ (4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

_____ (5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

_____ (6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

_____ (7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) ***Calibration and test methods***

_____ (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

_____ (2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

NOTES:

(i) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

(ii) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

_____ (3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

_____ (4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports [see also (k)(2)(x)].

_____ (5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples [see also (k)(2)(ix)].

_____ (6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall have written procedures which ensure that:

_____ (i) the NVLAP requirements are complied with;

_____ (ii) computer software, computers or automated equipment is documented and adequate for use;

_____ (iii) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

_____ (iv) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data [see also (f)(1)];

_____ (v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

_____ (8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory [see also (m)(2)].

(i) ***Handling of calibration and test items***

_____ (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time [see also (k)(2)(v)].

_____ (2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

_____ (3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned [see also (e)].

_____ (4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

_____ (5) Tamper-resistant seals shall be affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

NOTE: Tamper-resistant seals are sometimes affixed to equipment to prevent unauthorized access to areas where adjustments or critical components are located.

(j) ***Records***

_____ (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing [see also (c)(2)(iv)].

▸ **EXCEPTION:** The retention of all original observations, calculations, and
▸ derived data in the calibration record system is not a mandatory requirement
▸ for calibration laboratories, although it is encouraged as good laboratory
▸ practice.

_____ (2) All records (including those listed in (f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client [see also (b)(2)(ix), (c)(2)(xviii)].

NOTE: The period of retention shall be specified in the quality manual.

Record retention time specified: _____

(k) *Certificates and reports*

_____ (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used [see also (k)(4)].

▸ **NOTE:** It is recognized that the results of each calibration do not always
▸ result in the production of a calibration certificate or report. Whenever a
▸ certificate or report is produced, the above requirements shall be met.

(2) Each certificate or report shall include at least the following information:

_____ (i) a title, e.g., "Calibration Certificate," "Test Report" or "Test Certificate";

_____ (ii) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

_____ (iii) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

_____ (iv) name and address of client, where appropriate;

_____ (v) description and unambiguous identification of the item calibrated or tested [see also (i)(1)];

_____ (vi) characterization and condition of the calibration or test item;

_____ (vii) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

▸ **EXCEPTION:** Although it is encouraged as good laboratory practice, the
▸ requirement for inclusion of the date received is not mandatory for calibration
▸ laboratories.

_____ (viii) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

_____ (ix) reference to sampling procedure, where relevant [see also (h)(5)];

_____ (x) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions [see also (c)(2)(xv), (h)(4)];

_____ (xi) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

_____ (xii) a statement of the estimated uncertainty of the calibration or test result, where relevant;

_____ (xiii) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue [see also (c)(2)(vi)];

_____ (xiv) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

_____ (xv) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

_____ (xvi) a statement that the report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government;

_____ (xvii) the signature of an approved signatory for all test and calibration reports endorsed with the NVLAP logo;

▸ _____ (xviii) special limitations of use; and

▸ _____ (xix) traceability statement.

_____ (3) Where the certificate or report contains results of calibrations or tests performed by subcontractors, these results shall be clearly identified [see also (l)].

_____ (4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible [see also (k)(1)].

_____ (5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Test Report or Test Certificate), serial number ... (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of item (j).

_____ (6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report, or test certificate or amendment to a report or certificate.

NOTE: Such notification shall quantify the magnitude of error created in the calibration results. The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out of tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

_____ (7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the NVLAP requirements are met and that confidentiality is preserved.

_____ (8) Whenever a laboratory accredited by NVLAP issues a calibration or test report which contains data covered by the accreditation and also data not covered by the accreditation, it must clearly identify in its records, and in the report to the client, specifically which calibration or test method(s), or portion of a calibration or test method(s), was not covered by the accreditation. The laboratory must also inform the client, before the fact, when calibrations or tests requested are not covered by the accreditation.

NVLAP policy regarding calibration and test reports issued by an accredited laboratory, which reference the laboratory's accredited status, requires that any calibration or test report containing data from calibrations or tests which are not covered by the accreditation include:

_____ (i) a statement at the beginning of the report prominently indicating, "This report contains data which are not covered by the NVLAP accreditation"; and

_____ (ii) a clear indication of which data are not covered by the accreditation.

The laboratory must not misrepresent its accreditation. When a client requires or requests accredited services and any of the requested services are not covered by the accreditation, the client must be so advised.

(l) ***Subcontracting of calibration or testing*** [see also (k)(3)]

_____ (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

_____ (2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

_____ (3) A NVLAP-accredited laboratory intending to subcontract testing or calibration work that will be performed and reported as meeting NVLAP procedures and criteria must:

_____ (i) have in its quality manual a subcontracting policy compatible with the NVLAP policy, with a description of the procedures for administering and implementing those actions to demonstrate the conformance and consistency of the subcontracted laboratory to perform according to NVLAP procedures;

_____ (ii) place the subcontracted work with a laboratory that maintains accreditation established by NVLAP shown by a current NVLAP Lab Code, or provide and maintain current records that demonstrate that the subcontracted laboratory is competent to perform the test(s) or calibration(s) and that it operates in a manner consistent with and in conformance to NVLAP criteria for accreditation;

_____ (iii) clearly identify in its records, and in the report to the client, exactly which data were obtained by the NVLAP-accredited laboratory and which data were obtained by the subcontractor, NVLAP-accredited or not;

_____ (iv) inform its client, before the fact, that it intends to subcontract for completion of all or a portion of the client's work; and

_____ (v) include at the beginning of the report the name, address, and contact person of the subcontracted laboratory(ies), and one of the following statements, as appropriate:

if NVLAP-accredited

"This report contains data which were produced by a subcontracted laboratory **ACCREDITED (NVLAP LAB CODE)** for the calibration or test methods performed"

if not NVLAP-accredited

"This report contains data which were produced by a subcontracted laboratory **NOT ACCREDITED** for the calibration or test methods performed."

The requirements of this section do not supersede any regulation, law, contract specification, or other related conditions which require NVLAP accreditation.

(m) ***Outside support services and supplies***

_____ (1) Where the laboratory procures outside services and supplies in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

_____ (2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned [see also (h)(8)].

_____ (3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) ***Complaints*** [see also (c)(2)(xvii)]

_____ (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

_____ (2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the NVLAP requirements or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with item (c)(3).

(o) ***Measuring and test equipment (M & TE)***

NOTE: This section applies to the control of measuring and test equipment (M & TE) used to assure that supplies and services comply with prescribed customer requirements. It is based in large part on the requirements found in government audit standards such as MIL-STD 45662A, and is found in Part II of the ANSI/NCSL Z540-1-1994 (Draft) standard.

(1) General requirements for M & TE

_____ (i) The supplier shall establish and document a system to control the calibration/verification of M & TE.

_____ (ii) M & TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with sections 285.33(b) through (n).

_____ (iii) The supplier shall have a program to recall for calibration or verification, or remove from service, M & TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning because of mishandling, misuse, or unusual results.

_____ (iv) All operations performed by the supplier in compliance with these requirements shall be subject to customer verification at unscheduled intervals.

_____ (v) The supplier shall carry out, or arrange to have carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with these requirements.

- Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.

- Plans and procedures for the audits shall be documented. The conduct of the audit and any subsequent corrective action shall also be documented.

(2) Detailed requirements for M & TE

_____ (i) Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M & TE and measurement standards. The description shall be sufficient to satisfy each requirement of section 285.33(o) and any deviations shall be submitted with supporting documentation to the customer for approval.

_____ (ii) Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of items (f)(1), (g)(1), and (h)(2).

_____ (iii) Environmental conditions: M & TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

_____ (iv) Intervals of calibration and verification: M & TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M & TE will remain in-tolerance throughout the interval. Intervals shall be established for all M & TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

_____ (v) Calibration procedures: Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of items (h)(1) and (h)(2).

_____ (vi) Out-of-tolerance conditions: If any M & TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

_____ (vii) Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with these requirements.

_____ (viii) Calibration sources: M & TE requiring calibration shall be calibrated or verified by laboratories that comply with sections 285.33(b) through (n).

_____ (ix) Records: These requirements shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M & TE. The records for M & TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).

_____ (x) Calibration status: M & TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.

_____ (xi) Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to section 285.33 (l) to the degree necessary to assure compliance with contractual requirements. NVLAP accreditation of the subcontractor's laboratory can serve as the basis for compliance with this requirement.

_____ (xii) Storage and handling: M & TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.

NVLAP LAB CODE: _____

GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

NVLAP LAB CODE:

GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

APPENDIX C

SPECIFIC OPERATIONS CHECKLIST

NVLAP LAB CODE: _____

CHEMICAL CALIBRATION: PROVIDERS OF PROFICIENCY TESTING SPECIFIC OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses specific accreditation criteria prescribed in applicable sections of NIST Handbook 150-19.

Place an "X" beside any of the checklist items that represent a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments on this list or on the comment sheet(s). Place a check beside all other items you observed or verified at the provider's facility.

1 Organization and management

(See General Operations Checklist.)

2 Quality system, audit and review

_____ 2.1 The provider shall have the appropriate versions of the following documents available for reference:

_____ 2.1.1 NIST Handbook 150, *NVLAP Procedures and General Requirements*, March 1994;

_____ 2.1.2 NIST Handbook 150-19, *NVLAP Chemical Calibration: Providers of Proficiency Testing*, June 1999;

_____ 2.1.3 USEPA *National Standards for Water Proficiency Testing Studies: Criteria Document*, December 1998;

_____ 2.1.4 *NELAC Standards*, July 2 1998;

_____ 2.1.5 ISO Guide 30, *Terms and definitions used in connection with reference materials*, 1992;

_____ 2.1.6 ISO Guide 34, *Quality system guidelines for the production of reference materials*, 1996;

_____ 2.1.7 ISO Guide 43, *Proficiency testing by interlaboratory comparisons, Part 1 and Part 2*, 1997;

_____ 2.1.8 ISO/IEC/BIPM, *Guide to the Expression of Uncertainty in Measurement*, 1993; or ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*;

_____ 2.1.9 AOAC, *The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories*, 1993.

_____ 2.2 The provider's quality documentation contains procedures or instructions describing the following:

_____ 2.2.1 training of staff and documentation of the performance of analysts and technical staff;

_____ 2.2.2 sample custody and handling procedures, and procedures for ensuring the prevention of contamination or degradation of proficiency test materials or their component materials;

_____ 2.2.3 equipment maintenance, calibration, and verification;

_____ 2.2.4 operation of proficiency tests, including registration of laboratories under test, distribution of materials and instructions, and collection of data;

_____ 2.2.5 data processing for proficiency tests, and generation and distribution of reports; and

_____ 2.2.6 security of data and reports.

_____ 2.3 The provider shall conduct an internal audit at least annually to verify that its operations are in compliance with its quality manual and this program.

3 Personnel

_____ 3.1 The provider shall ensure that staff members are aware of the extent of their area(s) of responsibility.

_____ 3.2 The provider shall maintain documentation for each staff member that contains:

_____ 3.2.1 staff member's title and description of that job position;

_____ 3.2.2 job and quality assurance responsibilities;

_____ 3.2.3 résumé;

_____ 3.2.4 training;

_____ 3.2.5 assigned procedures and duties; and

_____ 3.2.6 results of periodic testing performance reviews.

_____ 3.3 The provider shall have a description of its staff training program including its criteria for successful completion.

_____ 3.4 Analysts and technical supervisors shall participate in some form of continuing education, such as formal course work, in-house education, and technical meetings,

and have access to journals, publications, and other information that describe advances in the field.

4 Accommodation (facilities) and environment

_____ 4.1 The provider shall maintain a facility that:

_____ 4.1.1 provides a safe work environment for all employees;

_____ 4.1.2 permits safe handling of any chemical used for any purpose; and

_____ 4.1.3 prevents contamination or degradation of proficiency test materials and of the raw materials from which they are prepared.

5 Equipment and reference materials

_____ 5.1 The provider shall maintain equipment and reference materials appropriate to the proficiency test materials being prepared and value-assigned.

_____ 5.1.1 Appropriate Standard Reference Materials from NIST will be available for use, together with the certificates that accompany the SRMs.

_____ 5.1.2 SRMs will be properly stored and used according to the instructions given on the certificate.

_____ 5.1.3 Analytical and other laboratory equipment will be properly maintained, calibrated, and as necessary, validated together with the analytical methods used by the laboratory.

6 Measurement traceability and calibration

_____ 6.1 Calibrations, value-assignments, and overall analytical verifications are performed by properly trained staff using Standard Reference Materials traceable to NIST, when available. When NIST certified reference materials are not available, appropriate reference materials certified by other national and international bodies may be used.

_____ 6.2 Reference materials shall be stored and used according to the instructions given on their certificate and guarded from degradation and contamination during storage and use. Care will be given to verifying that the correct certificate is available for each reference material and that the expiration date given on the certificate for the material has not passed.

7 Calibration and test methods

_____ 7.1 Starting materials will be verified for identity and assessed for purity or composition as appropriate.

_____ 7.2 Corrections for component purity will be applied prior to giving assigned values to proficiency test materials.

_____ 7.3 Analyses and test methods may be designed by the provider, but any such methods will have demonstrated overall validations. Methods designed by the provider will produce results of sufficient accuracy to meet the specifications of the proficiency tests for which they are intended.

_____ 7.4 Materials to be used as proficiency test materials will be verified with respect to assigned values, uncertainty, homogeneity, stability, and suitability for intended use in a given program (e.g., suitability of a PT material/study design for use with program-designated performance evaluation criteria to be used by the provider to evaluate laboratories under test).

NOTE: Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries, having Mutual Recognition Agreements with NIST, where applicable.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*, 1993, or ANSI/NCSL Z540-2-1997, shall be used as the basis for the expression of uncertainty of the measurement. NIST Technical Note 1297, September 1994, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement*. A guide is also available that deals expressly with analytical chemistry. It is *Quantifying Uncertainty in Analytical Measurements* (English edition), produced by Eurachem and distributed by BSI Customer Services, 389 Chiswick High Road, London, W4 4AL, United Kingdom. Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of analytical accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

NOTE: One suitable approach for the homogeneity testing of test items is described in The *International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories: Appendix II: A Recommended Procedure for Testing Materials for Sufficient Homogeneity*.

_____ 7.5 Materials will be tested for effects of shipment during proficiency test studies.

8 Handling of calibration and test items

_____ 8.1 The laboratory shall have a material log system used to uniquely identify proficiency test materials and their components, and to document processing, storage, and use of the materials. {The system will be consistent with applicable USEPA requirements.} The log shall, at a minimum, include:

_____ 8.1.1 date of receipt of the material;

_____ 8.1.2 the condition of the material;

_____ 8.1.3 documentation of acceptance or rejection of material, including reasons in any case of rejection;

_____ 8.1.4 a unique laboratory identification number for each material and for each test sample, thereof; and

_____ 8.1.5 the initials of the person making the above entries in the material log book.

_____ 8.2 Where there is any doubt as to the proficiency test material's suitability for use (e.g., a mismatch between identification and description), the laboratory shall have a procedure for resolving the problem. This action shall be documented.

_____ 8.3 Upon receipt of raw materials and chemicals to be used in preparing proficiency test materials, any abnormalities or departures from standard condition as prescribed in the relevant procedures shall be recorded. Where there is any doubt as to the material's suitability for use, or where the material does not conform to the description provided, corrective action shall be taken.

_____ 8.4 The provider shall have documented procedures and appropriate facilities to avoid deterioration or damage to proficiency test materials, during storage, handling, preparation, and analysis; any relevant instructions provided with the material shall be followed. Where materials have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored, and recorded where necessary. Where a material or portion of material is to be held secure (for example, for reasons of record, safety, or value, or to enable check analyses to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured materials or portions concerned [see also item 4 of this checklist].

_____ 8.5 The provider shall have documented procedures for the receipt, retention, or safe disposal of test materials, including all provisions necessary to protect the organization's integrity.

_____ 8.6 The provider shall have and use documented procedures for producing proficiency test materials having assigned values for analytes that differ from batch to batch randomly and cover, over time, the required range established by USEPA.

9 Records

_____ 9.1 The provider's quality system documentation shall have written procedures for the storage and retrieval of records.

_____ 9.2 Records are stored in a logical fashion allowing retrieval within one working day.

_____ 9.3 The provider shall have documentation, either electronic backup or "paper" hard copy, to verify survival of original data if computer systems are used for primary data retention.

_____ 9.4 The provider shall ensure that the analyst or proficiency testing professional signs (or initials) and dates the original data.

_____ 9.5 The following records are maintained for a minimum of 5 years:

_____ 9.5.1 materials log;

_____ 9.5.2 original data collected by analyst;

_____ 9.5.3 identity of personnel involved in sample preparation and value-assignment;

_____ 9.5.4 analytical data, including assigned values and uncertainties;

_____ 9.5.5 quality control activities and results;

_____ 9.5.6 proficiency test results of the laboratories under test and summary reports;

_____ 9.5.7 equipment and maintenance;

_____ 9.5.8 test reports; and

_____ 9.5.9 records of all actions taken in response to testing complaints.

10 Certificates and reports

(See General Operations Checklist.)

11 Subcontracting of calibration or testing

(See General Operations Checklist.)

12 Outside support services and supplies

(See General Operations Checklist.)

13 Complaints

(See General Operations Checklist.)

14 Operation of proficiency test studies

_____ 14.1 In addition to the requirements in the General Operations Checklist, the provider will be assessed in the following specifics:

_____ 14.1.1 Parameter assigned values with associated uncertainties are established and provided to NIST in a secure manner prior to the distribution of materials for each proficiency test study and are not changed on an ad hoc basis. For cases where values are assigned based on study data, this requirement is not applicable. A description of the PT material composition and any required dilutions by the laboratory under test are also provided to the Analytical Chemistry Division (ACD) of NIST.

_____ 14.1.2 All calendar dates set for a given proficiency study are adhered to closely, including completion of data processing and reporting of results.

_____ 14.1.3 Reports to all participants are issued on the same day.

_____ 14.1.4 Complaints by laboratories under test regarding specific analytical data are resolved in a timely fashion and documented for review by ACD of NIST.

_____ 14.1.5 The name, title, and signature of the Approved Signatory accepting technical responsibility for the tests and test report, and the secure identification code assigned to the laboratory under test, are available for each laboratory under test.

_____ 14.1.6 The name(s) and address(es) of the accrediting body(ies) to whom the PT results are to be reported for the specific subject of the proficiency test study are available for each laboratory under test for each study.

_____ 14.1.7 All applicable reports are developed and distributed according to current USEPA criteria.

_____ 14.2 The provider follows procedures that promote equal challenge among test studies conducted by different providers. Procedures employed will include, but not be limited to, those given below.

_____ 14.2.1 Each completed set of test study data will be examined by the provider for anomalous patterns for each analyte. Any analyte that provides anomalous results because of previously unrecognized significant inhomogeneity, instability, inaccurately assigned value, or other loss of integrity of the PT material will not be used to evaluate laboratories under test. At a minimum, the following will be considered:

_____ 14.2.1.1 displacement from the expected mean for results of the laboratories under test;

_____ 14.2.1.2 unusual dispersion of results;

_____ 14.2.1.3 unusual pass-fail results;

_____ 14.2.1.4 unexpected changes from earlier tests; and

_____ 14.2.1.5 any indication that the challenge of the proficiency test study may have provided a challenge that was either too easy or too difficult.

_____ 14.2.2 Any observed anomalies will be described to NIST, in a written study discussion report, together with any indications as to the cause of the anomalies.

_____ 14.2.3 The provider cooperates with NIST in any research into, or investigation of, the anomalies that may be necessary.

_____ 14.2.4 The provider appropriately identifies in all reports any analyte that provides anomalous study results because of previously unrecognized inhomogeneity, instability, or inaccurate assigned values.

_____ 14.3 The provider will have documentation available demonstrating that all applicable shipping and safety regulations are met, and that material distribution is done in a controlled manner, including the provisions that:

_____ 14.3.1 Material Safety Data Sheets (MSDS) will be available for all materials that require them and evidence must indicate they are appropriately used as required.

_____ 14.3.2 Clear and appropriate instructions to the laboratory under test will be available for all proficiency test studies currently being conducted or that have been conducted during the period of accreditation of the provider of proficiency testing. Instruction sets more than five years old will not be requested by assessors for review.

_____ 14.3.3 Material shipment procedures should be checked to assure that adequate consideration is given to protection of material quality and stability.

_____ 14.3.4 Shipping records should provide sufficient information to track material custody in the event a recall is required.

_____ 14.4 Instructions to laboratories under test will provide adequate guidance to assure that they correctly format and transmit the data that they return. The instructions should include warnings to the laboratory under test that they are not to reveal their results, or any other aspect of the test in which they have participated, to any unauthorized person or other laboratory until the test provider has announced the test study is concluded.

_____ 14.5 The data collected in a proficiency test study will be processed according to written procedures and criteria. The procedures will provide:

_____ 14.5.1 accurate data processing;

_____ 14.5.2 fair and equal treatment of laboratory results; and

_____ 14.5.3 clear reporting of laboratory status with respect to the criteria for acceptable performance.

_____ 14.6 Results of each proficiency test study will be available in electronic data formats specified by USEPA. For each study the results will be provided in four forms:

_____ 14.6.1 study discussion report, available for wide distribution, describing the general outcome of the study and describing any anomalies;

_____ 14.6.2 study summary report, available for wide distribution, and revealing no individual laboratory results;

_____ 14.6.3 individual laboratory evaluation reports, so coded as to completely obscure which laboratory was the source of the data; and

_____ 14.6.4 uncoded laboratory evaluation reports.

_____ 14.7 The laboratory must have, and demonstrate adherence to, a plan for distribution and security of proficiency test results. The plan must contain adequate controls that tested laboratories will be assured that their uncoded results will be made available only to authorized recipients.

PPT SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

NVLAP LAB CODE: _____

PPT SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

APPENDIX D

PROCEDURES FOR TESTING THE PROFICIENCY OF PROVIDERS

PROCEDURES FOR TESTING THE PROFICIENCY OF PROVIDERS

Proficiency testing by NIST of providers focuses primarily on assessing the proficiency of the providers in value-assigning proficiency test materials. Other critical aspects of the conduct of the proficiency test studies will be assessed by monitoring the providers' sets of completed study data, review of the providers' quality documentation, and at on-site audits.

The proficiency testing program for evaluation of providers of proficiency testing services will be conducted by technical divisions of the National Institute of Standards and Technology. Testing, including the initial test of a new applicant for accreditation, will follow one of two models as described below.

A. Direct Proficiency Testing

(1) The direct proficiency testing program will be conducted by the Analytical Chemistry Division of the National Institute of Standards and Technology (NIST). Proficiency testing materials are chosen to test each provider's ability to follow a method and to achieve the proper accuracy and precision.

(2) Each provider will be sent test materials, data sheets, and instructions for performing the test and reporting the results. Testing shall be conducted in accordance with a specific test method using the provider's normal operating procedures. Proficiency testing of a provider's laboratory shall not be contracted out to another laboratory. Any special NIST instructions shall also be followed. The special instructions are designed to ensure uniformity in procedures among participants. Completed data sheets shall be returned to NIST for analysis by a specified date. Failure to return the proficiency testing data sheets by the deadline date may result in failing that study.

(3) On occasion, the on-site assessor hand-carries proficiency test samples to a provider. These proficiency test samples, like all others analyzed by the laboratory, are to be listed or entered into the normal sample tracking and identification system for control and data recording. In these cases, the samples may be returned to the on-site assessor rather than stored at the laboratory.

(4) Results of the proficiency test study will be reported to the participants and in appropriate documents and reports. The identity and performance of individual providers will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during laboratory visits. Any problems indicated by proficiency testing will be discussed with appropriate laboratory personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based in part on satisfactory resolution of proficiency testing deficiencies.

(5) A proficiency test will use statistical and graphical techniques to examine the performance of each provider based on the results obtained on test samples, including the possibility of paired test samples.

If a laboratory exceeds the critical limits for the test sample (or either of the two paired test samples), it will fail the proficiency test. The critical lower and upper limits permissible for extreme data will vary depending upon the USEPA criteria for a given analyte in a given sample type.

Submitted results that are incomplete or that fall outside the critical limits will be considered as failing.

(6) If an accredited provider fails a proficiency test, it must do the following in order to maintain its accreditation:

(i) Provide, within 30 days of notification of failure, detailed, written documentation to NVLAP. The documentation must include an analysis of why the laboratory failed each part of the test, and what corrective actions (analyst training, revised procedures, quality assurance activities, etc.) it has taken to resolve its analytical problems so as to avoid similar errors in the future. Documented evidence that the corrective actions have been effectively implemented is required.

(ii) Participate successfully in the next study of proficiency testing.

(7) If a provider fails the same type of proficiency testing twice in succession or generally exhibits an erratic pattern in testing, NVLAP will review all current and previous proficiency testing results and advise the provider on what actions must be taken to correct the deficiency(ies). Failure to correct the deficiency(ies) may result in suspension or revocation of accreditation. In some cases, in order to regain accreditation, the provider shall undergo a complete on-site reassessment to determine the cause of the deficiency(ies), and to determine that effective corrective actions have been implemented. The provider shall provide NVLAP with documentation within 30 days of the reassessment, adequately demonstrating that any deficiency(ies) noted by the assessor has been satisfactorily resolved. Failure to perform fully satisfactorily in the on-site reassessment will result in the accreditation remaining suspended or revoked.

(8) The full cost of any on-site reassessment shall be paid in advance by the provider. NVLAP staff will make every effort to expedite these extraordinary assessments to give a provider every reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

(9) Failure to participate in a study of proficiency testing will result in immediate suspension of accreditation, and the provider shall successfully participate in the next regularly scheduled study in order to have its accreditation reinstated.

B. Indirect Proficiency Testing

(1) The indirect proficiency testing program will be conducted by the National Institute of Standards and Technology (NIST). Competence of the provider will be tested based on materials and proficiency test studies produced by that provider.

(2) For every proficiency test study operated by a provider, the provider will send to NIST, in advance of shipment of the proficiency test materials to the laboratories under test, the following:

(i) three units of the test material (as packaged for a laboratory under test),

(ii) the assigned value and its associated uncertainty for each analyte in the test material,

(iii) a description of the PT material composition (including identification and composition of the matrix), and

(iv) a description of any required dilutions by the laboratory under test.

Failure to submit samples and data by the deadline date may result in failing that study.

(3) As part of its evaluation of the provider's competence, NIST may analyze the submitted material, submit it to analyses by laboratories outside NIST, or otherwise use the material in any way it deems useful.

(4) Results of the proficiency testing of the providers will be reported to the participants and in appropriate documents and reports. The identity and performance of individual providers will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during visits to the provider. Any problems indicated by proficiency testing will be discussed with appropriate provider personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based in part on satisfactory resolution of proficiency testing deficiencies.

(5) Testing by NIST may take any or all of three forms:

(i) A material with assigned values and standard deviations submitted by a provider may be analyzed by NIST, or by an outside laboratory selected by NIST, with the results being compared to the values and standard deviations assigned by the provider under examination.

(ii) A material submitted as in (5) (i), above, may be compared relatively to those submitted by other providers and examined for differences exceeding the uncertainties reported by the providers.

(iii) A material submitted as in (5) (i), above, may be held for future analysis pending the outcome of a specific proficiency test study being conducted by the provider under examination. The material may be tested later, at the discretion of NIST. If appropriate, it will be tested in the event anomalous results arise in the proficiency test study.

(6) If an accredited provider fails an indirect proficiency test, it must do the following in order to maintain its accreditation:

(i) Provide, within 30 days of notification of failure, detailed, written documentation to NVLAP. The documentation must include an analysis of why the provider failed each part of the test, and what corrective actions (analyst training, revised procedures, quality assurance activities, etc.) it has taken to resolve its analytical problems so as to avoid similar errors in the future. Documented evidence that the corrective actions have been effectively implemented is required. In the event the failure has compromised a proficiency test study, the laboratories under test must be notified by the provider and offered a replacement "make-up" test study to demonstrate their proficiency.

(ii) Participate successfully in indirect proficiency testing during the next proficiency test study that the provider operates.

(7) If a provider fails an indirect proficiency test twice in succession or generally exhibits an erratic pattern in testing, NVLAP will review all current and previous proficiency testing results and advise the provider on what actions must be taken to correct the deficiency(ies). Failure to correct the deficiency(ies) may result in suspension or revocation of accreditation. In some cases, in order to regain accreditation, the provider shall undergo a complete on-site reassessment to determine the cause of the deficiency(ies), and to determine that effective corrective actions have been implemented. The provider shall provide NVLAP with documentation within 30 days of the reassessment, adequately demonstrating that any deficiency(ies) noted by the assessor has been satisfactorily resolved. Failure to perform fully satisfactorily in the on-site reassessment will result in the accreditation remaining suspended or revoked.

(8) The full cost of any on-site reassessment shall be paid in advance by the provider. NVLAP staff will make every effort to expedite these extraordinary assessments to give a provider every reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

(9) Failure to submit, in advance, material, assigned values, and uncertainties for each analyte in each study of proficiency testing will result in immediate suspension of accreditation, and the provider shall demonstrate proficiency through direct or indirect proficiency testing in order to have its accreditation reinstated.

Monitoring of Providers' Study Data for Indicators of Provider Performance

NIST technical divisions will also monitor providers' study data sets for anomalous patterns (e.g., expected versus actual study means, dispersion of laboratory results, failure rates, etc.; and from other comparisons with historical, other providers, and previous provider studies) and will report any observed significant deviation patterns to NVLAP. Because these anomalous patterns could be attributed to the performance of the specific set of participants in a given provider's study, they are considered to be only indicators of possible deficiencies in provider performance. (See Appendix C, item 14.2 for requirements for provider monitoring of each completed set of its PT study data for anomalous patterns for each analyte and reporting of any observed anomalies to NIST.)

APPENDIX E

PROFICIENCY TEST PROGRAM SELECTION LIST

NVLAP LAB CODE: _____

CHEMICAL CALIBRATION: PROVIDERS OF PROFICIENCY TESTING PROFICIENCY TEST PROGRAM SELECTION LIST

Instructions: Check each proficiency test program for which you are requesting accreditation.

USEPA Test Program Designations refer to:
- USEPA Water Supply (WSCHEM, WSRAD, WSMICRO) Proficiency Testing Studies
- USEPA Water Pollution (WPCHEM) Proficiency Testing Studies
- USEPA Discharge Monitoring Reduction Quality Assurance (DMRQACHEM) Proficiency Testing Studies

(Reference: "National Standards for Water Proficiency Testing Studies: Criteria Document," U.S. Environmental Protection Agency, December 30, 1998, Version)

Notes: 1) Study data for an analyte marked by an asterisk (*) are used by the provider to develop acceptance limits and the assigned value as described in USEPA "National Standards for Water Proficiency Testing Studies: Criteria Document" (U.S. Environmental Protection Agency, December 30, 1998, Version).

2) Program designations for USEPA radiochemistry (WSRAD) Proficiency Testing Studies will be available from NVLAP after the standards for these studies have been finalized by EPA in "National Standards for Water Proficiency Testing Studies: Criteria Document."

	NVLAP Code	***Proficiency Test Program Designation** (with listing of applicable analytes within each Program Designation)*
_____	20/U01	**USEPA WSCHEM Trace Metals** Antimony Arsenic Barium Beryllium Boron Cadmium Chromium Copper Lead Manganese Mercury (Source: 1:1 [mass:mass] mercuric oxide and methyl mercury chloride) Molybdenum Nickel Selenium Thallium Zinc

_____	20/U02	**USEPA WSCHEM Sodium** [Ref. USEPA WSCHEM Miscellaneous Analytes] Sodium
_____	20/U03	**USEPA WSCHEM Nitrate, Nitrite, Fluoride, and Orthophosphate** Fluoride Nitrate (as N) Nitrite (as N) Orthophosphate (as P)
_____	20/U04	**USEPA WSCHEM Bromate, Bromide, Chlorate, and Chlorite** [Ref. USEPA WSCHEM Inorganic Disinfection By-Products] Bromate Bromide Chlorate Chlorite
_____	20/U05	**USEPA WSCHEM Sulfate** [Ref. USEPA WSCHEM Miscellaneous Analytes] Sulfate
_____	20/U06	**USEPA WSCHEM Residual Free Chlorine** [Ref. USEPA WSCHEM Miscellaneous Analytes] *Residual Free Chlorine
_____	20/U07	**USEPA WSCHEM Cyanide** [Ref. USEPA WSCHEM Miscellaneous Analytes] Cyanide (Source: potassium cyanide)
_____	20/U08	**USEPA WSCHEM Asbestos** [Ref. USEPA WSCHEM Miscellaneous Analytes] *Asbestos (fibers/L)
_____	20/U09	**USEPA WSCHEM Volatile Organic Compounds (VOCs) Group I** [Ref. USEPA WSCHEM Regulated VOCs] Benzene Carbon tetrachloride Chlorobenzene 1,2-Dibromo-3-chloropropane (DBCP) 1,2-Dibromoethane (Ethylene dibromide, EDB) 1,2-Dichlorobenzene 1,4-Dichlorobenzene 1,2-Dichloroethane 1,1-Dichloroethene (1,1-Dichloroethylene) *cis*-1,2-Dichloroethene (*cis*-1,2-Dichloroethylene) *trans*-1,2-Dichloroethene (*trans*-1,2-Dichloroethylene) Dichloromethane (methylene chloride) 1,2-Dichloropropane Ethylbenzene

Styrene
Tetrachloroethene (Tetrachloroethylene)
Toluene
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethene (Trichloroethylene)
Vinyl chloride
Total Trihalomethanes (Source: bromodichloromethane, bromoform, dibromochloromethane, and/or chloroform)
Total Xylenes (Source: *o*-, *m*-, and *p*-xylene)

_____ 20/U10 **USEPA WSCHEM Volatile Organic Compounds (VOCs) Group II**
[Ref. USEPA WSCHEM Unregulated VOCs]
Bromobenzene
Bromochloromethane
Bromodichloromethane
Bromoform
Bromomethane
n-Butylbenzene
sec-Butylbenzene
tert-Butylbenzene
Chloroethane
Chloroform
Chloromethane
2-Chlorotoluene
4-Chlorotoluene
Dibromochloromethane (Chlorodibromomethane)
Dibromomethane
1,3-Dichlorobenzene
Dichlorodifluoromethane
1,1-Dichloroethane
1,3-Dichloropropane
2,2-Dichloropropane
1,1-Dichloropropene
cis-1,3-Dichloropropene
trans-1,3-Dichloropropene
Hexachlorobutadiene
Isopropylbenzene
4-Isopropyltoluene
n-Propylbenzene
1,1,1,2-Tetrachloroethane
1,1,2,2-Tetrachloroethane
1,2,3-Trichlorobenzene
Trichlorofluoromethane (Fluorotrichloromethane)
1,2,3-Trichloropropane
1,2,4-Trimethylbenzene
1,3,5-Trimethylbenzene

_____	20/U11	**USEPA WSCHEM Insecticides (Pesticides)** [Ref. USEPA WSCHEM Pesticides] Alachlor Aldrin Atrazine Dieldrin Endrin Heptachlor Heptachlor Epoxide (beta; Isomer B; heptachlor-2,3-exo-epoxide) Hexachlorobenzene γ-Hexachlorocyclohexane (lindane; gamma-HCH; γ-BHC) Hexachlorocyclopentadiene Methoxychlor Propachlor Simazine Trifluralin
_____	20/U12	**USEPA WSCHEM Herbicides (Pesticides)** Acifluorfen 2,4-D (Source: 2,4-D and 2,4-D butyl ester) Dalapon Dicamba Dinoseb Diquat dibromide (Diquat) (as monohydrate) Endothall (as monohydrate) Glyphosate Pentachlorophenol Picloram 2,4,5-TP (Silvex)
_____	20/U13	**USEPA WSCHEM Carbamate Pesticides** Aldicarb Aldicarb sulfone Aldicarb sulfoxide Carbofuran Methomyl Oxamyl
_____	20/U14	**USEPA WSCHEM Polycyclic Aromatic Hydrocarbon (PAH)** Benzo[a]pyrene
_____	20/U15	**USEPA WSCHEM Polychlorinated Biphenyls (PCBs/Aroclors)** Aroclor (as decachlorobiphenyl) (For Aroclors: 1016, 1232, 1242, 1248, 1254, and 1260)
_____	20/U16	**USEPA WSCHEM Toxaphene and Chlordane** [Ref. USEPA WSCHEM Pesticides] Chlordane (Total) Toxaphene (Total)

____	20/U17	**USEPA WSCHEM Dioxin (2,3,7,8-TCDD)** 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin
____	20/U18	**USEPA WSCHEM Adipate and Phthalate Esters** Bis(2-Ethylhexyl) adipate (Di(2-Ethylhexyl) adipate) Bis(2-Ethylhexyl) phthalate (Di(2-Ethylhexyl) phthalate)
____	20/U19	**USEPA WSCHEM Haloacetic Acids** [Ref. USEPA WSCHEM Disinfection By-Products] Bromochloroacetic acid Dibromoacetic acid Dichloroacetic acid Monobromoacetic acid Monochloroacetic acid Trichloroacetic acid
____	20/U20	**USEPA WSCHEM Chloral Hydrate** [Ref. USEPA WSCHEM Disinfection By-Products] Chloral hydrate
____	20/U21	**USEPA WSCHEM Total Organic Carbon (TOC)** [Ref. USEPA WSCHEM Miscellaneous Analytes] Total Organic Carbon (TOC)
____	20/U22	**USEPA WSCHEM Alkalinity (as $CaCO_3$)** [Ref. USEPA WSCHEM Miscellaneous Analytes] Alkalinity (as $CaCO_3$)
____	20/U23	**USEPA WSCHEM Calcium Hardness (as $CaCO_3$)** [Ref. USEPA WSCHEM Miscellaneous Analytes] Calcium Hardness (as $CaCO_3$)
____	20/U24	**USEPA WSCHEM Total Filterable Residue** [Ref. USEPA WSCHEM Miscellaneous Analytes] *Total Filterable Residue
____	20/U25	**USEPA WSCHEM pH** [Ref. USEPA WSCHEM Miscellaneous Analytes] pH
____	20/U26	**USEPA WSCHEM Turbidity** [Ref. USEPA WSCHEM Miscellaneous Analytes] Turbidity (NTU)
____	20/U27	**USEPA WSMICRO Coliform (Presence/Absence)** Total coliform Fecal coliform/*Escherichia coli*

_____ 20/U28 **USEPA WPCHEM/DMRQACHEM Trace Metals**
Aluminum
Antimony
Arsenic
Beryllium
Cadmium
Chromium
Cobalt
Copper
Iron
Lead
Manganese
Mercury (Source: 1:1 [mass:mass] mercuric oxide and methyl mercury chloride)
Molybdenum
Nickel
Selenium
Silver
Strontium
Thallium
Titanium
Vanadium
Zinc

_____ 20/U29 **USEPA WPCHEM Minerals: Calcium, Magnesium, Potassium, and Sodium**
[Ref. USEPA WPCHEM Minerals]
Calcium
Magnesium
Potassium
Sodium

_____ 20/U30 **USEPA WPCHEM Minerals: Chloride, Fluoride, and Sulfate**
[Ref. USEPA WPCHEM Minerals]
Chloride
Fluoride
Sulfate

_____ 20/U31 **USEPA WPCHEM/DMRQACHEM Nutrients**
Ammonia (as N)
Nitrate (as N)
Orthophosphate (as P)
Total Kjeldahl Nitrogen (TKN source: Glycine)
Total Phosphorus

_____ 20/U32 **USEPA WPCHEM/DMRQACHEM Total Residual Chlorine**
[Ref. USEPA WPCHEM/DMRQACHEM Miscellaneous Analytes]
*Total Residual Chlorine

____	20/U33	**USEPA WPCHEM/DMRQACHEM Cyanide** [Ref. USEPA WPCHEM/DMRQACHEM Miscellaneous Analytes] Total Cyanide (Source: Potassium ferricyanide)
____	20/U34	**USEPA WPCHEM Volatile Halocarbon Compounds** Bromodichloromethane Bromoform Carbon tetrachloride Chlorobenzene Chloroform Dibromochloromethane 1,2-Dichloroethane Dichloromethane (Methylene chloride) Tetrachloroethene 1,1,1-Trichloroethane Trichloroethene
____	20/U35	**USEPA WPCHEM Volatile Aromatic Compounds** Benzene 1,2-Dichlorobenzene 1,3-Dichlorobenzene 1,4-Dichlorobenzene Ethylbenzene Toluene
____	20/U36	**USEPA WPCHEM Chlorinated Pesticides** [Ref. USEPA WPCHEM Pesticides] Aldrin 4,4'-DDD 4,4'-DDE 4,4'-DDT Dieldrin Heptachlor Heptachlor epoxide (beta; Isomer B; heptachlor-2,3-exo-epoxide)
____	20/U37	**USEPA WPCHEM Chlordane** [Ref. USEPA WPCHEM Pesticides] Chlordane (total)
____	20/U38	**USEPA WPCHEM Polychlorinated Biphenyls (PCBs) (as Aroclors) in Water** Aroclor 1016 or Aroclor 1242 Aroclor 1232 Aroclor 1248 Aroclor 1254 Aroclor 1260

_____	20/U39	**USEPA WPCHEM Polychlorinated Biphenyls (PCBs) (as Aroclors) in Oil** Aroclor 1016 or Aroclor 1242 Aroclor 1254 Aroclor 1260
_____	20/U40	**USEPA WPCHEM/DMRQACHEM Total Phenolics** [Ref. USEPA WPCHEM/DMRQACHEM Miscellaneous Analytes] Total Phenolics (as phenol) (for colorimetric determination [with 4-aminoantipyrine]; Source: 2:1:1:1 [molar basis] Phenol:2-Chlorophenol:2,4-Dinitrophenol:2,4-Dichlorophenol)
_____	20/U41	**USEPA WPCHEM/DMRQACHEM Demands** (Source: Glucose and glutamic acid) Total Organic Carbon (TOC) Chemical Oxygen Demand (COD) 5-Day Biological Oxygen Demand (BOD) Carbonaceous Biological Oxygen Demand (CBOD)
_____	20/U42	**USEPA WPCHEM Total Alkalinity (as $CaCO_3$)** [Ref. USEPA WPCHEM Minerals] Total Alkalinity (as $CaCO_3$)
_____	20/U43	**USEPA WPCHEM Total Hardness (as $CaCO_3$)** [Ref. USEPA WPCHEM Minerals] Total Hardness (as $CaCO_3$)
_____	20/U44	**USEPA WPCHEM Total Dissolved Solids** [Ref. USEPA WPCHEM Minerals] *Total Dissolved Solids at 180 °C
_____	20/U45	**USEPA WPCHEM/DMRQACHEM Non-Filterable Residue** [Ref. USEPA WPCHEM/DMRQACHEM Miscellaneous Analytes] Non-Filterable Residue
_____	20/U46	**USEPA WPCHEM/DMRQACHEM Oil and Grease** [Ref. USEPA WPCHEM/DMRQACHEM Miscellaneous Analytes] Oil and Grease (Source: 1:1 [mass basis] Paraffin oil:cooking oil)
_____	20/U47	**USEPA WPCHEM/DMRQACHEM pH** [Ref. USEPA WPCHEM/DMRQACHEM Miscellaneous Analytes] pH
_____	20/U48	**USEPA WPCHEM Specific Conductance** [Ref. USEPA WPCHEM Minerals] *Specific Conductance [μS/cm at 25 °C (equivalent to EPA: μmhos/cm at 25 °C)]

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